

Electronic Drug Establishment Registration & Drug Listing in SPL Format

**GPhA – Fall Annual Workshop
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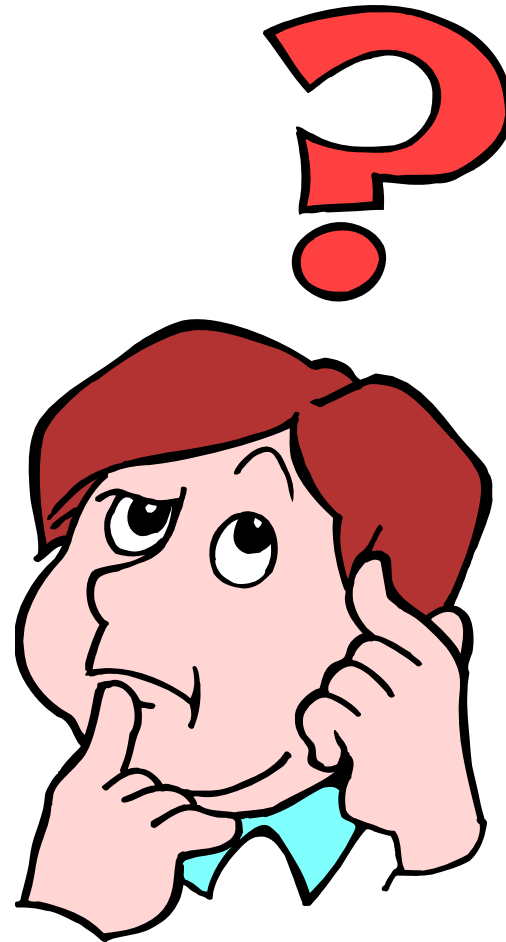
Overview

- Structured Product Labeling (SPL) Standard
- Transitioning from Paper to Electronic Drug Establishment Registration & Drug Listing
- Using SPL Format to Electronically Register Drug Establishments and List Drug Products

The Standard:

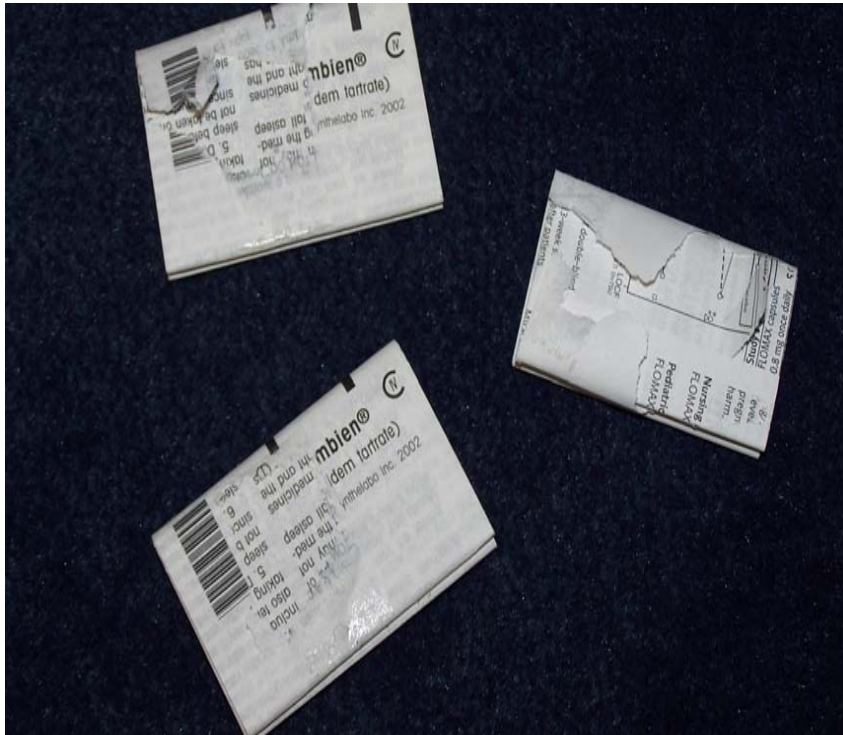
Structured Product Labeling (SPL)

- WHY CHANGE
THE **CONTENT OF**
LABELING THAT
HAS WORKED FOR
DECADES ????

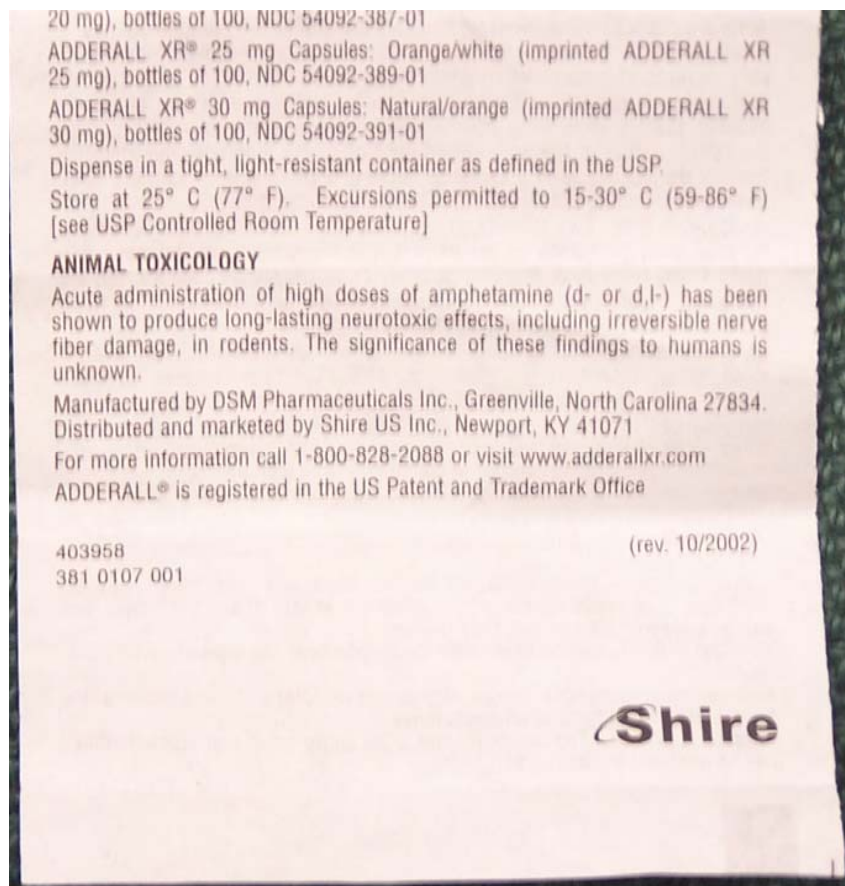




- Difficult to read - Font size and paper shape limits readability and duplication
- Difficult to access – distribution limited (e.g., pharmacy shelf)
- Difficult to use – information in paper labels cannot be accessed by computer systems



- The Labeling Rips when it is Removed!
- Critical data is missing.
- The Product can outdate the Labeling
- The Labeling is Often in the Container



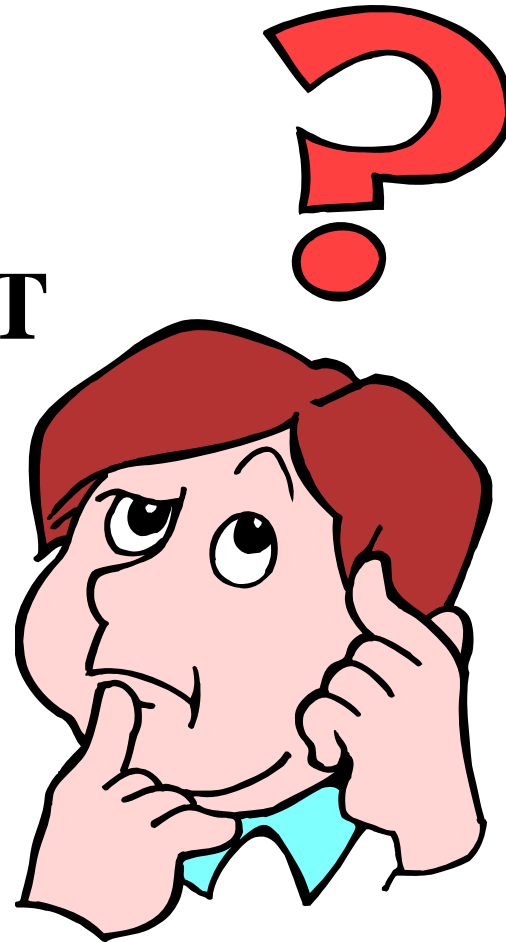
Labeling Sections are Difficult to Locate

The amount of intervening text **varies.**

Section locations occasionally **vary.**

This variability results in **wasted time and effort** looking for the critically needed drug information!

**WHY CHANGE
THE DRUG LISTING
AND ESTABLISHMENT
REGISTRATION
PROCESS THAT HAS
WORKED FOR
DECADES ????**



This is a complex form with multiple sections. It includes fields for 'Product Name', 'Manufacturer', 'Device Type', and 'Intended Use'. There are several checkboxes for 'Indications', 'Contraindications', and 'Warnings'. A table at the bottom contains columns for 'Device Name', 'Manufacturer', 'Device Type', 'Intended Use', 'Indications', 'Contraindications', and 'Warnings'.

This form features a large table with many rows and columns. The columns are labeled with various categories, and the rows are numbered. This layout is typical for a detailed data collection or inventory form.

This form is similar to the one above, featuring a large table with many rows and columns. The columns are labeled with various categories, and the rows are numbered. This layout is typical for a detailed data collection or inventory form.

- Eliminate duplicative and redundant data entry
- Automate processing of data in a submission type in electronic format in a manner that FDA can adequately process, review, and archive.

Structured Product Labeling

The Structured Product Labeling (SPL) is a document markup standard approved by Health Level Seven (HL7) and adopted by FDA as a mechanism for exchanging product information.

SPL's Goal is to make the labels and drug listing information:

- **People friendly**
 - Labeling content in electronic format
 - Improve readability
 - Better access
- **Computer friendly**
 - Product information that is **computer readable**
 - Structured labeling content and product listing elements - Computer can “find” a specific section of the labeling and specific elements within labeling and product listing sections.
- **Information system friendly**
 - Product information in computer readable form - Easily imported into information systems
 - FDA systems extract the coded data from the SPL file to accomplish drug establishment registration and drug product listing
- **Publicly available**
 - Content of Labeling (up-to-date version) is made available by the FDA thru NLM (DailyMed) to consumers and health information suppliers
 - Drug listing and establishment registration information is made available by the FDA via NDC Directory, Drug Firms Annual Registration, and future FACTS@FDA websites.

XML & XSL Stylesheet

- SPL is created using **EX**tensible **M**arkup **L**anguage (XML) – similar to HTML for webpages
- XML
 - Relatively human-legible
 - Machine readable
 - Tags (elements) permit search of key information
- XML Documents – created via Notepad, Word Pad, XML editing tools, SPL authoring tools, SPL conversion services, Xforms, etc...
- XSL Stylesheet – transforms the XML data to be viewed via web browser or printed documents

SPL Stylesheet View/Source Code

CONTRAINDICATIONS

Miracle Drug Injection is contraindicated in severe toxic central nervous system depression or comatose states from any cause and in individuals who are hypersensitive to this drug or have Parkinson's disease.

```
<component>
<section ID="_7CF4D228-65A6-6223-5A96-ECB4DBD620FC">
<id root="3A7D815A-A2B9-0389-5D92-4836E709B0FE" />
<code code="34070-3" codeSystem="2.16.840.1.113883.6.1" displayName="CONTRAINDICATIONS SECTION" />
<title mediaType="text/x-hl7-title+xml">CONTRAINDICATIONS</title>
<text><paragraph>Miracle Drug Injection is contraindicated in severe toxic central nervous system depression or comatose states from
any cause and in individuals who are hypersensitive to this drug or have Parkinson's disease.</paragraph></text>
<effectiveTime value="20070813" />
</section>
```

Communication

Verbal – Different Language

Bonjour

?

Hello

?

**Guten
Tag**



Communication

Verbal – Identical Language

Hello



Hello



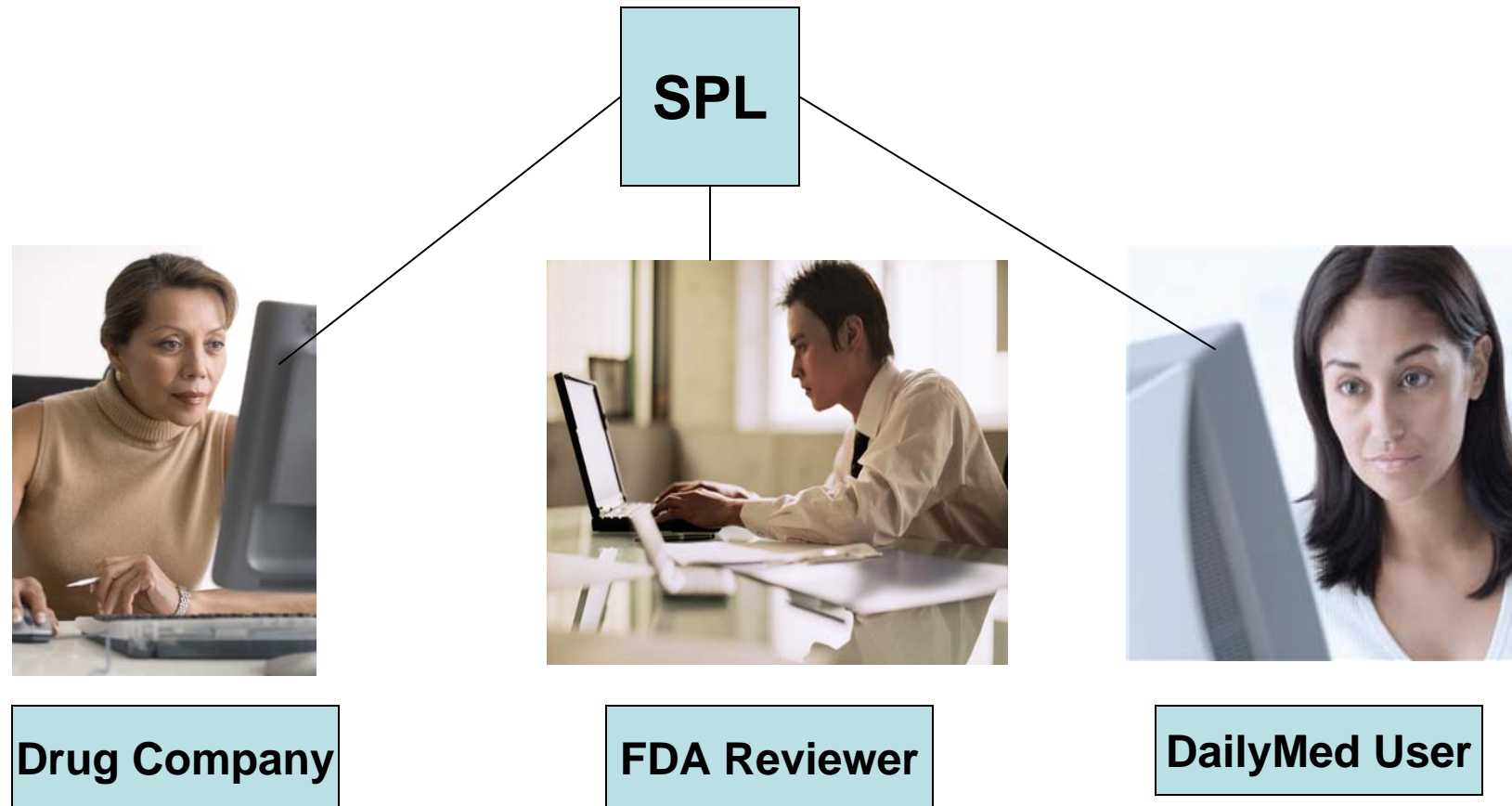
Hello



SPL - Language

- XML is a “language” that computers or systems can “understand”
- SPL – the “alphabet” (Only certain XML elements can be used.)
- SPL document is a “**message**” that is used to exchange or communicate product information (SPL content)
- Drug company
 - Creates SPL using SPL standard to communicate product information.
 - Submits SPL to FDA
- FDA
 - Processes and validates SPL document using SPL standard
 - Transmits SPL to public repository (DailyMed/FACTS@FDA)
- DailyMed/FACTS@FDA/Health Information Supplier
 - Imports SPL into their system that uses the SPL standard
 - Displays and uses SPL data (label, listing data elements, etc..)

Information Exchange SPL



SPL is a standard that is used by drug companies, FDA and public to exchange or review or view product information. All three entities use computer or systems that “understand” SPL

SPL Authoring Options

- SPL authoring tools helps you “write” SPL documents using the XML language.
- Tools to translate your data into the XML language.
- SPL conversion vendors – provide a conversion service
- SPL Authoring/Document Management Tools – to integrate processing SPL into your IT environment
- XForms - Tool to create SPL content of labeling documents and the future eList & eReg SPL documents. (similar to Word processing software) (used as a training tool)

Implementation of SPL

- Electronic Labeling Rule (ELR) (final) – effective June 2004
- Docket 92S-0251 memorandum – September 2004
 - CDER's readiness to accept content of labeling in PDF or XML format
- Content of Labeling guidance document (final) April 2005
- Docket 92S-0251 memorandum – October 2005
 - Eliminated use of PDF as the acceptable format of electronic Content of Labeling – only acceptable format is HL7 Structured Product Labeling XML standard
- Physician Labeling Rule (final) – effective June 2006
- Public Availability of Labeling Changes in "Changes Being Effected" Supplements (draft) – September 2006
- Indexing SPL guidance document (final) – June 2008
- Guidance for Industry: Providing Regulatory Submissions in Electronic Format – Drug Establishment Registration and Drug Listing (Draft) – July 2008
- SPL Docket 92S-0251 - Drug Establishment Registration and Drug Listing – July 2008

Transitioning from Paper to Electronic Drug Establishment Registration & Drug Listing

Transition from Paper to Electronic Drug Establishment Registration & Drug Listing

- Changes in FD&C Act require electronic registration of drug establishments and listing of human prescription drugs, OTC, animal drug, biologic products – September 2007
- Draft Guidance document for electronic drug establishment registration and listing – July 2008
- FDA is adopting the use of extensible markup language (XML) files in SPL format as the standard format for the exchange of drug establishment registration and drug listing information.

Benefits of Electronic Registration and Listing

- Electronic registration and listing process is more efficient and effective for industry and the Agency
- Accurate, up-to-date inventory of marketed drugs
- Eliminates data entry errors
- Well formed and properly created SPL files can be processed in minutes
- Use existing technology and data standard – **SPL (Used by FDA (CDER) since 2004)(Required by CDER in 2005)**
- SPL Release Four (R4) includes data elements needed to register drug establishments and list drug products

More Benefits of Electronic Registration and Listing

- Data maintenance
 - Content of Labeling and listing information in one file.
 - Registrant can list all it's establishments in one file.
 - Update information – Use one file instead of creating several paper forms and resubmit.
- Eliminates the use of paper forms for listing and registration
- 24-hour submission window – FDA Gateway
- Manage data using same source (files) as FDA
- Reduces the amount of time for FDA to receive and process your information.

Paper Listing Review



Electronic Listing Review



Terminology

- Only controlled terminology is permitted in SPL documents
- Terminology Resources
 - National Cancer Institute Thesaurus
 - FDA Data Standards Council's SPL web page (acceptable terms for use in SPL documents):
<http://www.fda.gov/oc/datacouncil/spl.html>

Terminology

- Each term in the controlled terminology is associated with a code
- The term (SPL Acceptable term or name) – displayed is for humans to understand and the code is for the computer to comprehend.
- The code can be utilized by international systems. The term may be displayed in two different languages in an international system; however the code can be the same.
 - Computers or information systems will understand the code for route of administration regardless of whatever the language is used to communicate to the consumer of the information

Data Elements

- Data Element:
 - A basic unit of identifiable and definable information. It occupies the space provided by a field in a record or a block on a form, and has an identifying name and value or values for expressing a specific fact. A data element is defined by its name, description, source, length, structure, and format.
- Product Data Elements (aka Drug Listing Data Elements)
 - Product data elements are **metadata** displayed via SPL stylesheet for purpose of review
 - Computer friendly information - product information which is tagged that permits search of key information.
 - Information system friendly – Medication information in computer readable form - Easily imported into information systems

Controlled Terminology

- Route of administration
- Dosage form
- Package type
- Units of measure and units of presentation
- Color
- Shape
- Coating (**obsolete for SPL R4 documents**)
- Size
- Scoring
- Imprint codes
- Symbols (**obsolete for SPL R4 documents**)
- SPL DEA Schedule
- Section headings
- Code system object identifiers (OIDs)
- Document Type including Content of Labeling Type
- Time Units: Unified Code for Units of Measure (UCUM)
- Substances/Unique Ingredient Identifiers (UNIIIs)
- Business Operation
- Marketing Category
- Marketing Status
- Equivalence Codes
- Flavor
- ISO 3166-1 Alpha-3 Country Code

Document/Product Types

- **BULK INGREDIENT**
- **ESTABLISHMENT REGISTRATION**
- **HUMAN OTC DRUG LABEL**
- **HUMAN PRESCRIPTION DRUG LABEL**
- **HUMAN PRESCRIPTION DRUG LABEL WITH HIGHLIGHTS**
- **LICENSE BLOOD INTERMEDIATES/PASTE LABEL**
- **LICENSED VACCINE BULK INTERMEDIATE LABEL**
- **MINIMALLY MANIPULATED CELLS LABEL**
- **NO CHANGE NOTIFICATION**
- **NON-STANDARDIZED ALLERGENIC LABEL**
- **NDC LABELER CODE REQUEST**
- **OTC ANIMAL DRUG LABEL**
- **OTC TYPE A MEDICATED ARTICLE ANIMAL DRUG LABEL**
- **OTC TYPE B MEDICATED FEED ANIMAL DRUG LABEL**
- **OTC TYPE C MEDICATED FEED ANIMAL DRUG LABEL**
- **OUT OF BUSINESS NOTIFICATION**
- **PRESCRIPTION ANIMAL DRUG LABEL**
- **VACCINE LABEL**
- **VFD TYPE A MEDICATED ARTICLE ANIMAL DRUG LABEL**
- **VFD TYPE B MEDICATED FEED ANIMAL DRUG LABEL**
- **VFD TYPE C MEDICATED FEED ANIMAL DRUG LABEL**

*** Codes intentionally excluded

Marketing Categories

- ANADA
- **ANDA**
- BLA
- **Bulk ingredient**
- Conditional NADA
- **Export only**
- IND
- NADA
- **NDA**
- **NDA authorized generic**
- **OTC monograph final**
- **OTC monograph not final**
- Unapproved homeopathic
- Unapproved medical gas
- Unapproved other

***Codes intentionally excluded

Transitioning from SPL R3 to R4

- Include a few more listing data elements
- Enter effectiveTime and version number prior to submitting to FDA

Transitioning from SPL R3 to R4

- GUIDs – Change case of uppercase letters to lower case.
- **IMPORTANT** – retain setID – just change the case of letters if uppercase is utilized.
- Delete coating and symbol product data elements from content of labeling/listing documents.
- Delete translation for units of measure for strength

Transitioning from SPL R3 to R4

- PLR SPL R4 documents:
 - Ensure that you enter title for release four SPL (drug names, Initial US approval date, etc...)
 - Boilerplate text for “title” is no longer rendered by stylesheet.
 - Include adverse reactions statement as free text
 - boilerplate text for this section no longer rendered by stylesheet in **SPL R4**
 - (boilerplate text still rendered for SPL R3 PLR documents)

Transitioning from Paper to Electronic: Drug Registration and Listing

- If you list electronically list your product(s) do not list the same products using paper (FDA Form 2657 or FDA Form 2658)
- If you register your drug establishment(s) electronically, do not register the same drug establishments using the paper (FDA Form 2656)

Replace Paper Forms (2656, 2657, 2658) with...

| | | | |
|--|-------------------|---|------------------|
| Save As... | Print Page | Print Form | |
| Form Approved - CME No. 0910-046, Expiration Date: December 31, 2007 | | See ONE Statement on Reverse | |
| DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION REGISTRATION OF DRUG ESTABLISHMENT/ LABELER CODE ASSIGNMENT <small>(in accordance with Public Law 102-227)</small> | | FOIA USE ONLY FOIA USE ONLY | |
| NOTICE: This report is required by law (21 C.F.R. 312.25-25.2). Failure to report on this will be imprisonment for not more than one year or a fine of not more than \$250,000. (21 C.F.R. 312.25-25.2) | | LABELER CODE REGISTRATION NUMBER | |
| SECTION A - SITE INFORMATION REPORTING ESTABLISHMENT | | STATE OF INC. | |
| SITE ADDRESS (No. R or S) (a) | | SITE TELEPHONE NUMBER () | |
| CITY | STATE | ZIP CODE | COUNTRY |
| <input type="checkbox"/> BUSINESS CATEGORY: <input type="checkbox"/> HUMAN <input type="checkbox"/> VETERINARY | | | |
| SITE MAILING ADDRESS (if different from above address) | | | |
| CITY | STATE | ZIP CODE | COUNTRY |
| | | SITE INTERNET/ELECTRONIC ADDRESS | |
| DOING BUSINESS AS (DGA) NAME OF FIRM (if applicable) | | | |
| PARENT COMPANY NAME | | | |
| REASON(S) FOR SUBMISSION | | | |
| <input type="checkbox"/> Firm Registration <input type="checkbox"/> Registration of Additional Site <input type="checkbox"/> Re-Registration <input type="checkbox"/> LAD Assignment <input type="checkbox"/> Name Change <input type="checkbox"/> Address Change <input type="checkbox"/> Mergers/acq. <input type="checkbox"/> New/Existing Business <input type="checkbox"/> Other (Name) | | TYPE OF OWNERSHIP <input type="checkbox"/> Sole Proprietorship <input type="checkbox"/> Partnership <input type="checkbox"/> Corp. Affn. <input type="checkbox"/> Corporation <input type="checkbox"/> Other _____ | |
| | | PERSON SUBMITTING DATA AND TELEPHONE | |
| | | BUSINESS TYPE <input type="checkbox"/> Distributor* <input type="checkbox"/> Foreign Country <input type="checkbox"/> Manufacturer <input type="checkbox"/> Importer <input type="checkbox"/> Analytical Lab <input type="checkbox"/> Supplier | |
| SECTION B - FIRM COMPLIANCE MAILING ADDRESS (For Annual, Warning Signal and/or Pen Correspondence) | | | |
| NUMBER AND STREET AND/OR P.O. BOX AND ATTENTION LINE and/or Internal Mail Code | | TELEPHONE NUMBER () | |
| CITY | STATE | ZIP CODE | COUNTRY |
| | | COMPLIANCE INTERNET/ELECTRONIC ADDRESS | |
| SECTION C - ADDITIONAL FIRM AND SITE INFORMATION | | | |
| NAME OF OWNER, PARTNER, OR OFFICER | | TITLE | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| OTHER FIRMS DOING BUSINESS AT THIS SITE | | | |
| LABELER CODE | FIRM NAME | LABELER CODE | FIRM NAME |
| | | | |
| SECTION D - SIGNATURE | | | |
| SIGNATURE OF AUTHORIZING OFFICIAL | | TITLE | DATE |
| | | | |
| <small>* DISTRIBUTORS CERTIFICATION: As a Distributor, I am submitting product listing information to the FDA on my own behalf. I have provided a copy of this certification (FDA Form 350) to the registered manufacturer(s). My signature and office number are listed below.</small> | | | |
| RETURN THIS FORM TO: FOOD AND DRUG ADMINISTRATION CDREGISTRATION REGISTRATION AND LISTING (HFD-32) 5600 PLAINFIELD AVE ROCKVILLE, MD 20857 (TOLL FREE) 1-877-664-6463 HAS 207 | | SIGNATURE OF DISTRIBUTOR DISTRIBUTOR'S TELEPHONE NUMBER () | |
| FORM FDA 2436 (06/07) (P/007) | | | |
| <small>NOTE: Validation of the form is not to be construed as FDA approval of the establishment or its products.</small> | | | |
| PREVIOUS EDITION IS OBSOLETE | | | |

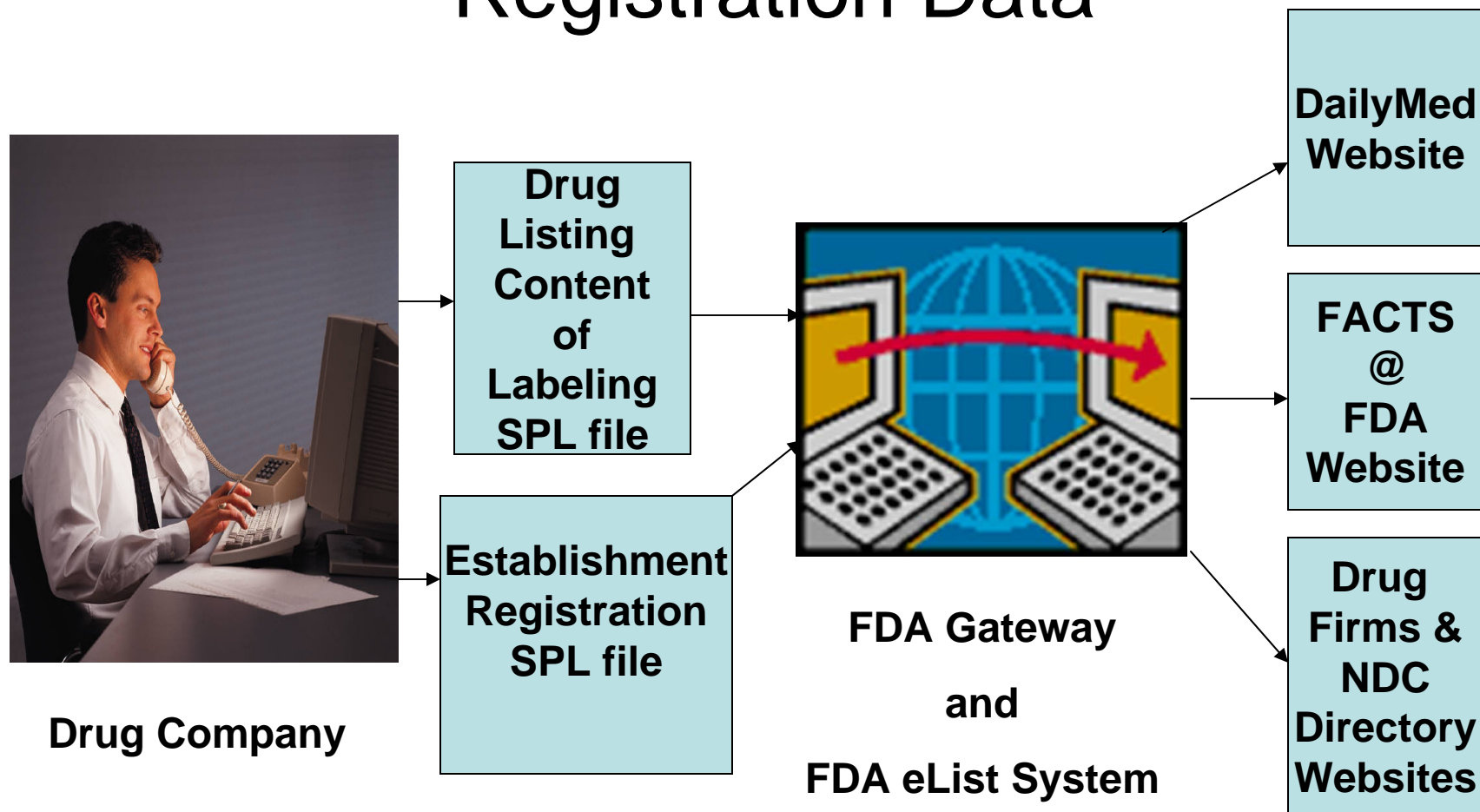
[illegible]

| Issue Date | Rev | Issue Date | Rev | Print Date | Print Date | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| <div style="display: flex; justify-content: space-between;"> <div> DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION </div> <div> FOR FIMA USE COUNTRY NO. </div> <div> FORM 283C (Rev. 10-1996) REPORTING FIRM </div> <div> ESTABLISHMENT REGISTRATION NO. </div> <div> REPORTING FIRM NO. CODE </div> <div> PRODUCT </div> </div> | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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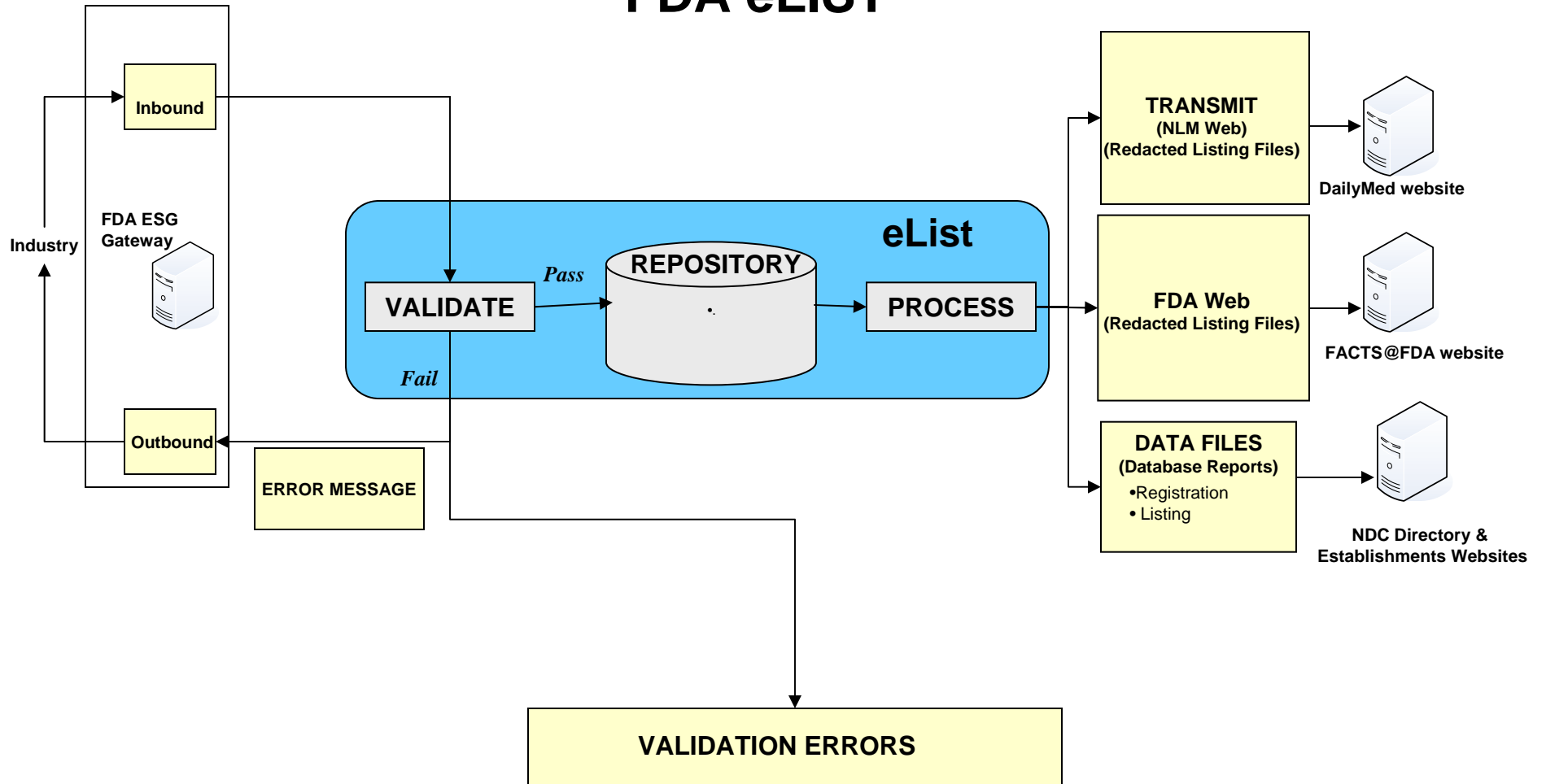
...three e-Files for Registration & Listing – SPL Format

- NDC Labeler Code Request
- Establishment Registration
- Content of labeling (CoL)/Listing

You Control the Published Electronic Drug Listing and Establishment Registration Data



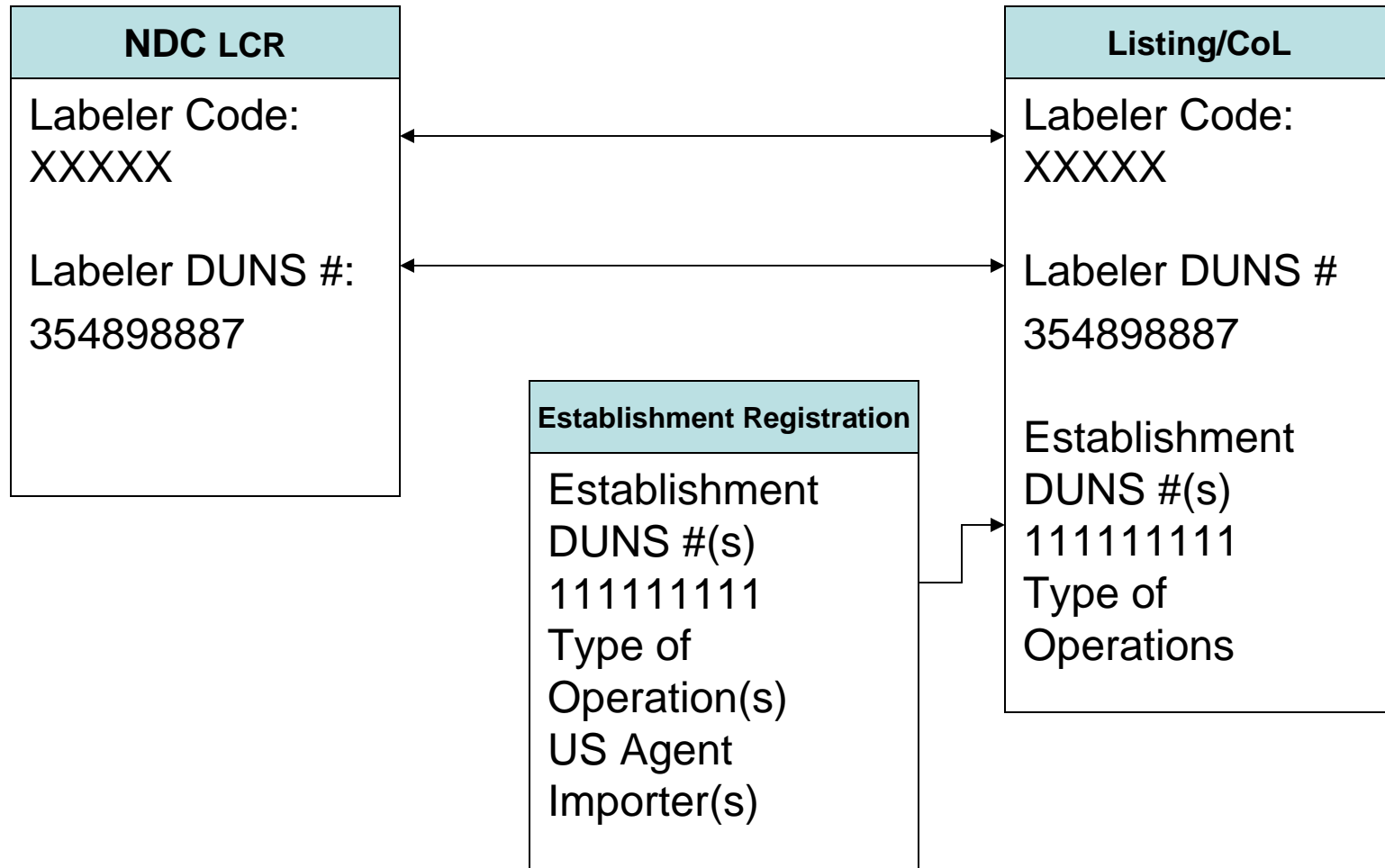
FDA eLIST



Order of Submissions

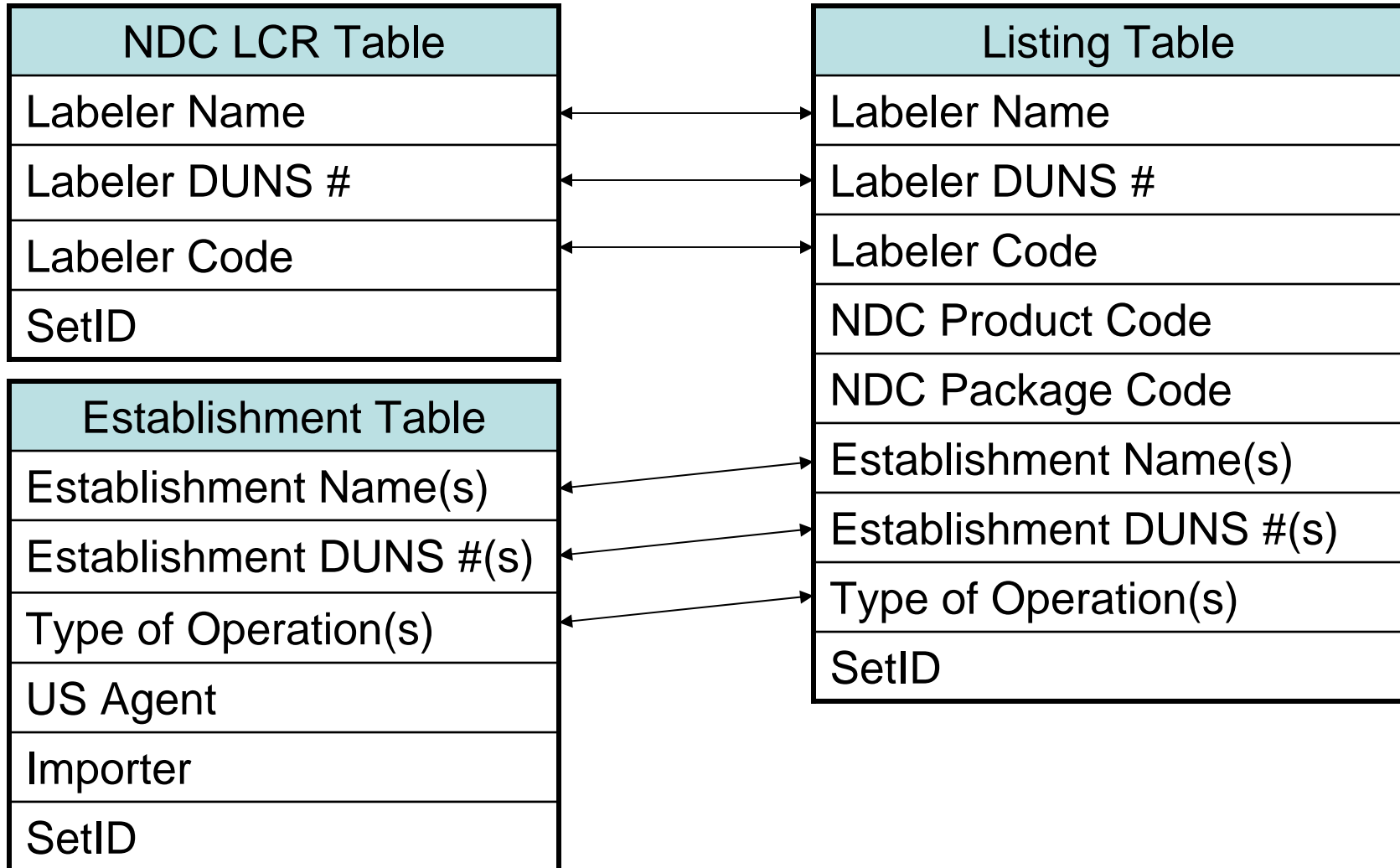
1. NDC Labeler Request (LCR) and Establishment Registration (ER) SPL
 2. CoL/Listing SPL
- CoL/Listing validates against data submitted in NDC LCR and ER SPL

Data Source – SPL Documents



eList Data Relationships

Mockup



Query Example Mockup

FDA eList System

Listed Product Verification

| | |
|----------------------|-----------------------------------|
| Establishment Search | NDC Package Code: XXXXX-XXX-X |
| | Establishment DUNS # 111111111 |

| Listing Database Table | |
|-------------------------|--------------------------------------|
| Field Name | Field Value |
| Labeler Name | Jaysonian Pharm |
| Labeler DUNS # | 354898887 |
| Labeler Code | XXXXX |
| NDC Product Code | XXXXX-XXX |
| NDC Package Code | XXXXX-XXX-X |
| Establishment Name(s) | Pham Pharma |
| Establishment DUNS #(s) | 111111111 |
| Type of Operation(s) | Manufacture |
| SetID | 027005a5-4c40-4931-85cd-79933f99e338 |

Product Package

**Miracle Drug XR
(good drug) Tablets**

30 Tablets
NDC: XXXXX-XXXX-X
DUNS #111111111

**Important: not a depiction of
FDA's System – for demo
only**

Using the SPL Format to Electronically Register Drug Establishments and List Drug Products

Document Tracking Information

Basic information for identifying the SPL document:

- **Document ID:** is a Globally Unique Identifier (GUID) and is unique for each version of the document. Letters used in a GUID are lower case.
- **Document Type:** The <code> is the LOINC code which provides information on the document type.
- **Effective Time:** provides a date reference to the SPL version including the year, month and day as yyyyymmdd.
- **SetID:** is a GUID and is a unique identifier for the document that remains constant through all versions/revisions of the document.
- **Version number:** is an integer greater than zero that provides a sequence to the versions of the document.

NDC Labeler Code Request

NDC Labeler Code Request Data

- **Document Information**

- Type of document
- ID
- Set ID
- Version Number
- Effective Time

- **Labeler**

- Name
- DUNS Number
- NDC Labeler Code

- **Contact**

- Name
- Mailing Address
- City
- State
- Country
- Postal Code
- Telephone Number
- Email Address

NDC Labeler Code Request Xforms View

| HL7 SPL - NDC Labeler Code Request v 0.71 | |
|--|---|
| <div>Open Save As Save</div> | |
| <div>NDC Labeler Code Request Preview</div> | |
| Document Information | |
| Type of document | NDC LABELER CODE REQUEST |
| ID | 3267a844-378f-4020-912b-43babb77001d |
| Set ID | 8d24aab5-8f91-42ca-9637-997a3d223e5c |
| Version Number | 1 |
| Effective Time | 20080909 |
| example(YYYYMMDD) | |
| Labeler | |
| Name | Acme Pharmaceuticals, Inc |
| DUNS Number | 111119999 |
| NDC Labeler Code | 44444 |
| <div>Add NDC Labeler Code Delete NDC Labeler Code</div> | |
| Contact | |
| Name | Charles Daniels |
| Mailing Address | 44 Pembroke Drive |
| City | Rockville |
| State | MD |
| Country | USA |
| Postal Code | 20888 |
| Telephone Number | tel:+1-888-888-4757 |
| Email Address | mailto:charles.daniels@acme-pharmaceuticals |
| example(tel:+1-201-555-1212) example(mailto:xportal@globalsubmit.com) | |

NDC Labeler Code Request SPL Document

Acme Pharmaceuticals, Inc

| | |
|----------------------------|--------------------------|
| Product Information | |
| Product Type | NDC LABELER CODE REQUEST |

Labeler - Acme Pharmaceuticals, Inc (111119999) **NDC Labeler Code:** 44444

| Contact | Address | Telephone Number | Email Address |
|-----------------|---|------------------|--|
| Charles Daniels | Address: 44 Pembroke Drive City, State, Zip: Rockville , MD, 20888 Country: USA | +1-888-888-4757 | charles.daniels@acme-pharmaceuticals.com |

Revised: 09/2008

Acme Pharmaceuticals, Inc

NDC LCR SPL Scenarios

- **Requesting a new NDC Labeler Code**
 - Fill out the *NDC Labeler Code request* as described in sections 2.1 through 2.4 leaving the NDC Labeler Code field empty.
 - Requests for NDC Labeler Codes are individually evaluated prior to entry into the NDC System. The initial request will be automatically stopped because there is no NDC Labeler Code provided and is diverted to a FDA reviewer. Once the evaluation is completed, the response to the request is directed to the designated contact person.
 - Once the NDC Labeler Code is assigned, open the original SPL file and add the newly assigned NDC Labeler Code and resubmit the corrected file.
- **Initial electronic submission when NDC Labeler Code already assigned**
 - Fill out the *NDC Labeler Code request*. Only one NDC Labeler Code is included in an SPL file. In other words, use a different setId root for each NDC Labeler Code request.

NDC LCR SPL

Scenarios cont...

- **Correct SPL file validation error**
 - If an SPL file cannot be processed because of a validation error, a report on the validation error is sent from FDA to the contact person. Open the SPL file and correct the errors.
- **Correct a mistake in an SPL file just submitted**
 - Open the SPL file, correct the mistake, and fill in a **new id root** and **new version number** with the **original setId root** and the appropriate effective time.

NDC LCR SPL

Scenarios cont...

- **Update the NDC Labeler Code information**
 - Open the previous SPL file and fill in the new information without changing the other existing information. Fill in a **new id root** and **new version number** with the **original setld root** and the appropriate effective time.
- **Requesting a second NDC Labeler Code**
 - Only one NDC Labeler Code is associated with each *NDC Labeler Code request*. If a second NDC Labeler Code is requested, fill out a separate SPL file with a **different setld root**. The labeler information and contact information is the same as the SPL file for the first NDC Labeler Code request

Establishment Registration

Establishment Registration Data

- **Document Information**

- Type of Document
- ID
- Set ID
- Version Number
- Effective Time

- **Registrant**

- Name
- DUNS Number

- **Registrant Contact**

- Name
- Mailing Address
- City
- State
- Country
- Postal Code
- Telephone Number
- Email Address

Establishment Registration Data (cont...)

- **Establishment**
 - Name
 - DUNS Number
 - FEI
 - Street Address
 - City
 - State
 - Country
 - Postal Code
 - Type of Operation(s)
- **Establishment Contact**
 - Name
 - Mailing Address
 - City
 - State
 - Country
 - Postal Code
 - Telephone Number
 - Email Address

Establishment Registration Data (cont...)

- **US Agent (if applicable)**
 - Name
 - DUNS number
 - Telephone Number
 - Email Address
- **Importer (if applicable)**
 - Name
 - DUNS number
 - Telephone Number
 - Email Address

Establishment Registration

SPL Xforms

| HL7 SPL - Establishment Registration v 0.71 | |
|--|--------------------------------------|
| <div>Open Save As Save</div> | |
| <div>Establishment Registration Preview</div> | |
| Document Information | |
| Type of Document | ESTABLISHMENT REGISTRATION |
| ID | 4ff69f20-6dc3-49ca-bb3c-0d589ff4c0b1 |
| Set ID | 118ec196-50d7-49b2-946a-831d29702818 |
| Version Number | 1 |
| Effective Time | 20080909 |
| example(YYYYMMDD) | |
| Registrant | |
| Name | Acme, Inc. |
| DUNS Number | 2223334441 |
| Registrant Contact | |
| Name | Deborah Tyler |
| Mailing Address | 222 Bonifant Avenue |
| City | Fort Washington |
| State | PA |
| Country | USA |
| Postal Code | 35295 |
| Telephone Number | tel:+1-800-435-4585 |
| Email Address | mailto:deborah.tyler@acme.com |
| example(tel:+1-201-555-1212) example(mailto:xportal@globalsubmit.com) | |

Establishment Registration

SPL Xforms cont...

| | | |
|--|-----------------------------|--|
| Establishment | | |
| Name | Acme Manufacturing, Inc. | |
| DUNS Number | 475859252 | |
| FEI | 35295835928 | |
| <input type="button" value="Add FEI"/> <input type="button" value="Delete FEI"/> | | |
| Street Address | 777 Sampson Street | |
| City | Mason | |
| State | PA | |
| Country | USA | |
| Postal Code | 35859 | |
| Type of Operation | manufacture ▼ | |
| <input type="button" value="Add Type of Operation"/> <input type="button" value="Delete Type of Operation"/> | | |
| Establishment Contact | | |
| Name | Pam Jamison | |
| Mailing Address | 777 Sampson Street | |
| City | Mason | |
| State | PA | |
| Country | USA | |
| Postal Code | 35859 | |
| Telephone Number | tel:+1-800-778-8359 | example(tel:+1-201-555-1212) |
| Email Address | mailto:pam.jamison@acme.com | example(mailto:xportal@globalsubmit.com) |
| <input type="button" value="Add US Agent"/> <input type="button" value="Delete US Agent"/> | | |
| <input type="button" value="Add Importer"/> <input type="button" value="Delete Importer"/> | | |

Establishment Registration

SPL Xforms cont...

| Establishment | |
|--|-----------------------------------|
| Name | Acme International |
| DUNS Number | 98583572 |
| FEI | 25835925829 |
| <input type="button" value="Add FEI"/> <input type="button" value="Delete FEI"/> | |
| Street Address | 33 Bleu Rue |
| City | Paris |
| State | |
| Country | FRA |
| Postal Code | 20583 |
| Type of Operation | manufacture |
| Type of Operation | analysis |
| <input type="button" value="Add Type of Operation"/> <input type="button" value="Delete Type of Operation"/> | |
| Establishment Contact | |
| Name | Etienne St. Champs |
| Mailing Address | 33 Bleu Rue |
| City | Paris |
| State | |
| Country | FRA |
| Postal Code | 20583 |
| Telephone Number | tel:+33-538-5859 |
| Email Address | mailto:etienne.st-champs@acme.com |

example(tel:+1-201-555-1212)

example(mailto:xportal@globalsubmit.com)

Establishment Registration

SPL Xforms cont...

| | | |
|--|------------------------------------|--|
| Establishment Contact | | |
| Name | Etienne St. Champs | |
| Mailing Address | 33 Bleu Rue | |
| City | Paris | |
| State | | |
| Country | FRA | |
| Postal Code | 20583 | |
| Telephone Number | tel:+33-538-5859 | example(tel:+1-201-555-1212) |
| Email Address | mailto:etienne.st-champs@acme.com | example(mailto:xportal@globalsubmit.com) |
| US Agent | | |
| Name | Acme USA | |
| DUNS number | 359582424 | |
| Telephone Number | tel:+1-800-999-5542 | example(tel:+1-201-555-1212) |
| Email Address | mailto:jacob.goodman@acme.com | example(mailto:xportal@globalsubmit.com) |
| <input type="button" value="Add US Agent"/> <input type="button" value="Delete US Agent"/> | | |
| Importer | | |
| Name | Franklin Imports | |
| DUNS number | 252597793 | |
| Telephone Number | tel:+1-888-444-5835 | example(tel:+1-201-555-1212) |
| Email Address | mailto:paula.johansen@franklin.com | example(mailto:xportal@globalsubmit.com) |
| <input type="button" value="Add Importer"/> <input type="button" value="Delete Importer"/> | | |
| <input type="button" value="Add Establishment"/> <input type="button" value="Delete Establishment"/> | | |

Establishment Registration SPL Document

| Product Information | |
|---------------------|----------------------------|
| Product Type | ESTABLISHMENT REGISTRATION |

| Registrant - Acme, Inc. (2223334441) | | | |
|--------------------------------------|--|------------------|------------------------|
| Contact | Address | Telephone Number | Email Address |
| Deborah Tyler | Address: 222 Bonifant Avenue City, State, Zip: Fort Washington, PA, 35295 Country: USA | +1-800-435-4585 | deborah.tyler@acme.com |

| Establishment | | | |
|--------------------------|---|------------------|----------------------|
| Name | Address | ID/FEI | Operations |
| Acme Manufacturing, Inc. | Address: 777 Sampson Street City, State, Zip: Mason, PA, 35859 Country: USA | 475859252 | manufacture |
| Contact | Address | Telephone Number | Email Address |
| Pam Jamison | Address: 777 Sampson Street City, State, Zip: Mason, PA, 35859 Country: USA | +1-800-778-8359 | pam.jamison@acme.com |

Establishment Registration

SPL Document cont...

| | | | |
|------------------------------|--|-------------------------|-----------------------------|
| | Country: FRA | | |
| Establishment | | | |
| Name | Address | ID/FEI | Operations |
| Acme International | Address: 33 Bleu Rue City, State, Zip: Paris, 20583 Country: FRA | 98583572 | manufacture, analysis |
| Contact | Address | Telephone Number | Email Address |
| Etienne St. Champs | Address: 33 Bleu Rue City, State, Zip: Paris, 20583 Country: FRA | +33-538-5859 | etienne.st-champs@acme.com |
| US Agent (ID) | Address | Telephone Number | Email Address |
| Acme USA (359582424) | | +1-800-999-5542 | jacob.goodman@acme.com |
| Importer (ID) | Address | Telephone Number | Email Address |
| Franklin Imports (252597793) | | +1-888-444-5835 | paula.johansen@franklin.com |

Revised: 09/2008

Establishment Information for Inactive Ingredient Manufacturers

- Establishment information for manufacturers of **inactive ingredients** in your products to be listed – does **NOT** need to be included in your **electronic drug listing SPL**.

Drug Listing Establishment Information for API Manufacturers

- Establishment information for manufacturers of your **active pharmaceutical ingredient (API)** used in your products – Recommendation that this information **should** be included in your **electronic drug listing document** (SPL file)

Establishment Registration Scenarios

- **Initial electronic submission for establishments already registered**
 - Registrants include information for all of their establishments in one *Establishment Registration* SPL file. Each establishment is in only one SPL file.
- **Correct SPL file validation error**
 - If an SPL file cannot be processed because of a validation error, a report on the validation error is sent from FDA to the contact person. Open the SPL file and correct the errors.

Establishment Registration Scenarios cont...

- **Correct a mistake in an SPL file just submitted**
 - Open the SPL file, correct the mistake, and fill in a **new id root** and **new version number** with the **original setld root** and the appropriate effective time.
- **Update information for a registered establishment**
 - Open the previous SPL file and fill in the new information without changing the other existing information. Fill in a **new id root** and **new version number** with the **original setld root** and the appropriate effective time.

Establishment Registration Scenarios cont...

- **Add a new establishment**
 - Open the previous SPL file and fill in the information on a new establishment without changing the information on the other establishments. Fill in a **new** id root and **new** version number with the **original** setId root and the appropriate effective time.

Establishment Registration

Scenarios cont...

- **No changes to registration information**
 - Each year when the information is updated, if there is no change, create an SPL file with the *document type* **No change notification** with a **new** id root and **new** version number with the **original** setId and the appropriate effective time. Registrant and establishment information is not included with an SPL file with the *document type* **No change notification**.
- **Registrant goes out of business**
 - If the registrant goes out of business, create an SPL file with the *document type* **Out of business notification** using a **new** id root and **new** version number with the **original** setId and the appropriate effective time. Registrant and establishment information is not included with an SPL file with the *document type* **Out of business notification**.

Content of Labeling/Listing

Content of Labeling/Listing Data

- **Document Information**

- Type of document
- ID
- Set ID
- Version Number
- Effective Time

Content of Labeling/Listing Data cont...

- **Drug Listing**
- **Labeler**
 - Name
 - DUNS Number
- **Registrant**
 - Name
 - DUNS number
 - Mark as Confidential
- **Establishment**
 - Name
 - DUNS number
 - Mark as Confidential
 - Type of operation
 - Product
 - ID (section ID)
 - Effective Time

Content of Labeling/Listing Data cont...

- **Product Information**
 - Proprietary Name
 - Proprietary Name Suffix
 - Non-Proprietary Name
 - NDC Product Code
 - Dosage Form
 - Source NDC Product Code (if applicable)
 - DEA Schedule (if applicable)
 - Route(s) of Administration
- **Active Ingredient**
 - Name(s)
 - Unique Ingredient Identifier(s) (UNII)
 - Strength
- **Reference Drug**
 - Name
 - Unique Ingredient Identifier (UNII)

Content of Labeling/Listing Data cont...

- **Active Moiety**
 - Name(s)
 - Unique Ingredient Identifier(s) (UNII)
 - Basis of Strength
- **Inactive Ingredient**
 - Name(s)
 - Unique Ingredient Identifier(s) (UNII)
 - Mark as Confidential
 - Strength
- **Flavor**
 - Name(s)
 - Original Text

Content of Labeling/Listing Data cont...

- **Imprint Information**

- Color(s)
 - Original Text
- Score
- Shape
 - Original Text
- Imprint Code
- Size
- Size Unit

Content of Labeling/Listing Data cont...

- **Marketing Date**
 - Product Status
 - Start Marketing Date
 - End Marketing Date (if applicable)
- **Marketing Category**
 - Marketing Category
 - Application or citation number
 - Application or citation number code system

Content of Labeling/Listing Data cont...

- **Packaging**
 - **Immediate packaging**
 - NDC Package Code (10 digit)
 - Quantity
 - Package Type
 - **Outer package**
 - NDC Package Code (10 digit)
 - Quantity
 - Package Type

Content of Labeling/Listing Data cont...

- **Product Parts**
 - Proprietary Name
 - Proprietary Name Suffix
 - Non-Proprietary Name
 - NDC Product Code
 - Dosage Form
 - Total Product Quantity
 - Source NDC Product Code (if applicable)
 - DEA Schedule (if applicable)
 - Route(s) of Administration

Content of Labeling/Listing cont...

- **Active Ingredient**
 - Name(s)
 - Unique Ingredient Identifier(s) (UNII)
 - Strength
- **Reference Drug**
 - Name
 - Unique Ingredient Identifier (UNII)
- **Active Moiety**
 - Name(s)
 - Unique Ingredient Identifier(s) (UNII)
 - Basis of Strength

Content of Labeling/Listing Data cont...

- **Inactive Ingredient**
 - Name(s)
 - Unique Ingredient Identifier(s) (UNII)
 - Mark as Confidential
 - Strength
- **Flavor**
 - Name(s)
 - Original Text
- **Imprint Information**
 - Color(s)
 - Original Text
 - Score
 - Shape
 - Original Text
 - Imprint Code
 - Size
 - Size Unit

Content of Labeling/Listing Data cont...

- **Marketing Date**
 - Product Status
 - Start Marketing Date
 - End Marketing Date (if applicable)
- **Marketing Category**
 - Marketing Category
 - Application or citation number
 - Application or citation number code system

Content of Labeling/Listing Data cont...

- **SPL Product Image** (location in slide is not indicative of placement in SPL)
- **Packaging**
 - **Immediate packaging**
 - NDC Package Code (10 digit)
 - Quantity
 - Package Type
 - **Outer package**
 - NDC Package Code (10 digit)
 - Quantity
 - Package Type

Drug Listing/CoL SPL Xforms

| HL7 SPL - Drug Listing v 0.71 | |
|--|--|
| <div>Open Save As Save</div> | |
| <div>Document Information Drug Listing Content of Labeling Preview</div> | |
| Document Information | |
| Type of document | <div>HUMAN PRESCRIPTION DRUG LABEL</div> |
| ID | <div>8c561834-cee2-4731-b9b9-cd9db64c030d</div> |
| Set ID | <div>11342435-a415-415a-81b6-d68d23b90b83</div> |
| Version Number | <div>1</div> |
| Effective Time | <div>20090909</div> <div>example(YYYYMMDD)</div> |

Drug Listing/CoL SPL Xforms cont...

| HL7 SPL - Drug Listing v 0.71 | |
|--|---------------------------|
| <div>Open Save As Save</div> | |
| <div>Document Information Drug Listing Content of Labeling Preview</div> | |
| Labeler | |
| Name | Acme Pharmaceuticals, Inc |
| DUNS Number | 111119999 |
| Registrant | |
| Name | |
| DUNS number | |
| Mark as Confidential | <input type="checkbox"/> |
| Establishment | |
| Name | Acme Manufacturing, Inc. |
| DUNS number | 475859252 |
| Mark as Confidential | <input type="checkbox"/> |
| Type of operation | manufacture |
| <div>Add Type of Operation Delete Type of Operation</div> | |
| Establishment | |
| Name | Acme International |
| DUNS number | 98583572 |
| Mark as Confidential | <input type="checkbox"/> |
| Type of operation | manufacture |
| Type of operation | analysis |
| <div>Add Type of Operation Delete Type of Operation</div> | |
| <div>Add Establishment Delete Establishment</div> | |

Drug Listing/CoL SPL Xforms cont...

| | | |
|----------------|--------------------------------------|-------------------|
| ID | 82df6f14-84c2-4d98-9551-fb4f4527e921 | |
| Effective Time | 20090909 | example(YYYYMMDD) |

Product Information

| | |
|-------------------------|-----------|
| Proprietary Name | Miracle |
| Proprietary Name Suffix | XR |
| Non-Proprietary Name | Good Drug |
| NDC Product Code | 44444-333 |
| Dosage Form | TABLET |

Add Source NDC Product Code Delete Source NDC Product Code

| | |
|--------------|-----|
| DEA Schedule | CII |
|--------------|-----|

Add DEA Schedule Delete DEA Schedule

| | |
|-------------------------|------|
| Route of Administration | ORAL |
|-------------------------|------|

Add Route of Administration Delete Route of Administration

Active Ingredient

| | | | | |
|-------------------------------------|-----------|----|----|---|
| Name | Good Drug | | | |
| Unique Ingredient Identifier (UNII) | 245895XFT | | | |
| Strength | 25 | mg | in | 1 |

Add Reference drug Delete Reference drug

Active Moiety

| | |
|-------------------------------------|---------------|
| Name | active moiety |
| Unique Ingredient Identifier (UNII) | 538TW3529 |

Add Active Moiety Delete Active Moiety

| | |
|-------------------|-------------------|
| Basis of Strength | Active Ingredient |
|-------------------|-------------------|

Drug Listing/CoL

SPL Xforms cont...

| | |
|--|--|
| Inactive Ingredient | |
| Name | <input type="text" value="Inactive ingredient one"/> |
| Unique Ingredient Identifier (UNII) | <input type="text" value="X5385925T3"/> |
| Mark as Confidential | <input checked="" type="checkbox"/> |
| <input type="button" value="Add Strength"/> | <input type="button" value="Delete Strength"/> |
| <input type="button" value="Add Inactive Ingredient"/> <input type="button" value="Delete Inactive Ingredient"/> | |
| Flavor | |
| Name | <input type="text" value="CITRUS"/> |
| Original Text | <input type="text" value="citrus-flavored"/> |
| <input type="button" value="Add Flavor"/> | <input type="button" value="Delete Flavor"/> |
| Imprint Information | |
| Color | <input type="text" value="yellow"/> |
| Original Text | <input type="text" value="yellow-orange"/> |
| <input type="button" value="Add Color"/> | <input type="button" value="Delete Color"/> |
| Score | <input type="text" value="Two even pieces"/> |
| Shape | <input type="text" value="ROUND"/> |
| Original Text | <input type="text" value="ROUND"/> |
| Imprint Code | <input type="text" value="AC;25;mg"/> |
| Size | <input type="text" value="18"/> |
| Size Unit | <input type="text" value="mm"/> |
| <input type="button" value="Add Imprint"/> | <input type="button" value="Delete Imprint"/> |

Drug Listing/CoL

SPL Xforms cont...

| | |
|-----------------------|----------|
| Marketing Date | |
| Product Status | Active |
| Start Marketing Date | 20070413 |
| example(YYYYMMDD) | |

| | |
|--|---|
| Marketing Category | |
| Marketing Category | NDA |
| Application or citation number | NDA024380 |
| Add Application or citation number | Delete Application or citation number |
| Application or citation number code system | Application |
| Add Application or citation number code system | Delete Application or citation number code system |
| Add Product image | Delete Product image |

| | | | |
|-----------------------------|----------------|-------------------|----------------------|
| Packaging | | | |
| NDC Package Code (10 digit) | 44444-333-50 | | |
| Quantity | 50 | | |
| Package Type | TABLET | | |
| NDC Package Code (10 digit) | 44444-333-10 | | |
| Quantity | 1 | | |
| Package Type | BOTTLE | | |
| CARTON | | | |
| Add Package | Delete Package | Add Outer Package | Delete Outer Package |

| | |
|----------------------|---------------------|
| Product Parts | |
| Add Product Part | Delete Product Part |
| Add Product | Delete Product |

Drug Listing/CoL SPL Xforms cont...

| | | | | | |
|------------------------------|--|---|--|---------------------|--|
| Open | | Save As | | Save | |
| Document Information | | Drug Listing | | Content of Labeling | |
| Content of Labeling | | | | | |
| Title | | <input type="text" value="Miracle XR"/> | | | |
| Add Title | | Delete Title | | | |
| Section | | <input type="text" value="DESCRIPTION SECTION"/> | | | |
| Add Hyperlink ID | | Delete Hyperlink ID | | | |
| ID | | <input type="text" value="49f13953-fe26-475b-af74-d2f3b1ff2fea"/> | | | |
| Title | | <input type="text" value="Description"/> | | | |
| Add Title | | Delete Title | | | |
| Effective time | | <input type="text" value="20070531"/> | | | |
| Add Effective time | | Delete Effective time | | | |
| Add Highlight | | Delete Highlight | | | |
| Section Text | | | | | |
| Description text placeholder | | | | | |
| Edit | | | | | |
| Observation Media | | | | | |
| Add Media | | Delete Media | | | |
| Add Sub-Section | | Delete Sub-Section | | | |
| Add Section | | Delete Section | | | |

Drug Listing/CoL SPL Document

MIRACLE XR - good drug tablet
Acme Pharmaceuticals, Inc

Miracle XR

Description

Description text placeholder

Drug Listing/CoL SPL Document

MIRACLE XR

good drug tablet

Product Information

| | | | |
|-------------------------|-------------------------|---------------------------|-----------|
| Product Type | HUMAN PRESCRIPTION DRUG | NDC Product Code (Source) | 44444-333 |
| Route of Administration | ORAL | DEA Schedule | CII |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---------------------------|-------------------|----------|
| Good Drug (active moiety) | Good Drug | 25 mg |

Inactive Ingredients

| Ingredient Name | Strength |
|-------------------------|----------|
| Inactive ingredient one | |

Product Characteristics

| | | | |
|----------|--------------------------|--------------|----------|
| Color | yellow (yellow-orange) | Score | 2 pieces |
| Shape | ROUND (ROUND) | Size | 18mm |
| Flavor | CITRUS (citrus-flavored) | Imprint Code | AC;25;mg |
| Contains | | | |

Packaging

| # | NDC | Package Description | Multilevel Packaging |
|---|--------------|-----------------------|--|
| 1 | 44444-333-10 | 1 BOTTLE In 1 CARTON | contains a BOTTLE (44444-333-50) |
| 1 | 44444-333-50 | 50 TABLET In 1 BOTTLE | This package is contained within the CARTON (44444-333-10) |

Drug Listing/CoL SPL Document

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| NDA | NDA024380 | 04/13/2007 | |

Labeler - Acme Pharmaceuticals, Inc (111119999)

Establishment

| Name | Address | ID/FEI | Operations |
|--------------------------|---------|-----------|-------------|
| Acme Manufacturing, Inc. | | 475859252 | manufacture |

Establishment

| Name | Address | ID/FEI | Operations |
|--------------------|---------|----------|-----------------------|
| Acme International | | 98583572 | manufacture, analysis |

Content of Labeling/Listing Scenarios

- **Initial listing submission when release 3 SPL file previously submitted**
 - Update the previous SPL release 3 file to an SPL release 4 file with the additional drug listing information and submit a new SPL file using a **new** id and **new** version number with the **original** setId and the appropriate effective time.
- **Initial listing submission with drugs previously listed**
 - The drug listing information is provided in a single SPL file. More than one drug products are included in a single SPL file when the products relate to the same content of labeling. Each drug product is included in only one SPL file unless it is being repacked or relabeled. Note that drug listing includes all jpg files associated with the content of labeling. The drug listing SPL file is separate from the SPL file for NDC Labeler Code request and the SPL file for establishment registration.

Content of Labeling/Listing

Scenarios cont...

- **Initial listing submission when the private label distributor provides the SPL file**
 - If the private label distributor chooses to provide the SPL file with the drug listing information, the private label distributor includes all of the information that would have been supplied by the registrant including all establishments involved in the manufacturing and processing of the drug product. The registrant does **not** submit a drug listing SPL file for this drug product. If the private label distributor chooses not to provide the SPL file with the drug listing information, then the registrant provides the SPL file.
- **Initial listing submission when the registrant provides the SPL file for a drug made for a private label distributor**
 - If the private label distributor chooses not to provide the SPL file with the drug listing information, then the registrant provides the SPL file. The registrant includes the name of the private label distributor as the labeler, itself as the registrant, and all establishments involved in the manufacturing and processing of the drug.

Content of Labeling/Listing

Scenarios cont...

- **Initial listing submission with more than one registrant involved**
 - When more than one registrant is involved in manufacturing and processing a single drug product (e.g., contract manufacturers), only one registrant provides the SPL file with the drug listing information for the drug product. The registrant who provides the SPL file includes, in addition to its own establishments, all establishments of the other registrants involved in the manufacturing and processing of the drug product.
- **Initial listing submission for bulk ingredients**
 - The registrant provides the SPL file with the drug listing information for the bulk drug ingredients (e.g., active pharmaceutical ingredient).

Content of Labeling/Listing Scenarios cont...

- **Initial listing submission for a registrant using a marketed bulk ingredient**
 - The registrant provides the SPL file with the drug listing information for its drug product. The registrant includes the NDC Product Code for the marketed bulk drug ingredient as the source NDC or the establishments used in manufacturing or processing the bulk ingredient.
- **Initial listing submission for a registrant repacking or relabeling a marketed drug product**
 - The repacker or relabeler provides the SPL file with the drug listing information for its drug product including the NDC Product Code for the source marketed drug product.

Content of Labeling/Listing Scenarios cont...

- **Initial listing submission for a kit including two or more drug products**
 - The registrant or private label distributor provides the SPL file with the drug listing information for its kit. The SPL file also includes drug listing information for each drug product in the kit (component) including NDC Product Codes and NDC Package Codes, if applicable.
- **Correct SPL file validation error**
 - If an SPL file cannot be processed because of a validation error, a report on the validation error is sent from FDA to the contact person. Open the SPL file and correct the errors.

Content of Labeling/Listing Scenarios cont...

- **Correct a mistake in an SPL file just submitted**
 - Open the SPL file, correct the mistake, and fill in a **new id root** and **new version number** with the **original setld root** and the appropriate effective time.
- **Update information for a listed drug product**
 - Open the previous SPL file and fill in the new information without changing the other existing information. Fill in a **new id root** and **new version number** with the **original setld root** and the appropriate effective time.

Content of Labeling/Listing

Scenarios cont...

- **Add a new drug product**
 - Open the previous SPL file and fill in the information on a new drug product without changing the information on the other drug products. Fill in a **new** id root and **new** version number with the **original** setId root and the appropriate effective time.
- **Discontinue a previously listed drug product**
 - Open the previous SPL file and update the marketing activity with the expiration date for the last lot released for the specific drug product information without changing the existing information on the other drug products. Fill in a new SPL file using a **new** id and **new** version number with the **original** setId and the appropriate effective time. Once the drug is discontinued, open the most recent SPL file and remove the specific drug product information without changing the existing information on the other drug products. Fill in a new SPL file using a **new** id and **new** version number with the **original** setId and the appropriate effective time.

Content of Labeling/Listing Scenarios cont...

- **Change in content of labeling not requiring prior approval**
 - Open the previous SPL file and change the content of labeling without changing the other existing drug listing information. Fill in the new SPL file using a **new** id and **new** version number with the **original** setId and the appropriate effective time.
- **Add a package configuration**
 - Open the previous SPL file and add the new package configuration without changing the other existing drug listing information. Fill in the new SPL file using a **new** id and **new** version number with the **original** setId and the appropriate effective time.
- **Remove a package configuration**
 - Open the previous SPL file and remove the specific package configuration without changing the other drug listing information. Fill in the new SPL file using a **new** id and **new** version number with the **original** setId and the appropriate effective time.

Marketing/File Management

CoL/Listing Files

- Status of product
 - Active: on the market
 - Completed: when marketing is done the drug is no longer going to be available on the market.
 - Active or completed timestamp: effectiveTime value.
- Low value
 - Time on the market
 - Determines release of CoL/Listing SPL to public
- High value
 - Time off the market (e.g. the expiration date of the last lot released to the market.)

Submitting SPL R4 Files

- **Naming the file:** The root id from the document identifiers is used for the name of the **SPL** file with the extension “xml”.
- **Sending the file:**
 - SPL files including all associated image files are placed in a **folder** and sent through the FDA Gateway. **One SPL document** (and image files, if applicable) **per folder**.
 - Instructions for using the FDA Gateway are found on the FDA Web site at <http://www.fda.gov/esg>. The name of the “center” and the “type of submission” are used to properly route the files. For electronic drug registration and listing, the center is “OC” and the type of submission is “SPL”.

Xforms Demo

SPL R4 Documentation

(Recommended Reading)

- Guidance for Industry: Providing Regulatory Submissions in Electronic Format – Drug Establishment Registration and Drug Listing (Draft)
- Structured Product Labeling Implementation Guide for FDA Drug Establishment Registration and Drug Listing v1.0
- Structured Product Labeling Validation Procedures for Drug Establishment Registration and Drug Listing v1.0
- Instructions for using Electronic Drug Establishment Registration and Drug Listing XForms v1.0
- SPL Docket 92S-0251 - Drug Establishment Registration and Drug Listing

*****These documents were used as resources for this presentation**

Collaboration with Industry

- HL7 SPL Implementation Working Group
- Drug companies (workshops, individual assistance)
- Vendors (workshops, individual assistance)
- Contact FDA to request 1:1 SPL R4 training sessions

Participation in Voluntary Pilot Program

- Start with NDC Labeler Code Request
 - Receive feedback from Agency
 - Slowly acclimate to the new electronic eList system
 - Prepare for June 1, 2009

Recommendations

- Review your entire SPL document prior to submission
- Use the current SPL schema, SPL stylesheet, SPL implementation guide, and other SPL technical documents available on the FDA DSC website
- When submitting technical questions regarding SPL XML coding please send an example, if possible.

Accomplishments

- FDA (CDER) has been using the SPL standard for almost 3 years
- Quality of SPL documents has improved significantly since October 2005
- DailyMed - **1.6 million** hits per month – (New website less than 3 years old)
- Over **4,039** SPL documents posted on DailyMed (as of October 2008)

Stay Informed

- FDA Data Standards Council website listserv
 - Over **22,000** listserv subscribers as of October 2008
 - <http://www.fda.gov/oc/datacouncil/>



SPL-related Technical Assistance/Questions

- SPL e-mail account (spl@fda.hhs.gov)

Thank you!

Questions?